

In re Appln. of Hulse et al.
Serial No. 08/853,422

REMARKS

The Office Action mailed January 9, 1998, rejected claims 1, 2, 4, 6-8, and 14-17 under 35 U.S.C. § 102(b) as anticipated by Neward '944. Further, under 35 U.S.C. § 103(a), it rejected claims 3, 5, and 18 as obvious over Neward '944, and claims 11-13, 19, and 20 as obvious over Neward '944 in view of Neward '086. The Office Action further indicated that claims 9 and 10 would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claim. Claim 9 has been rewritten in independent form as added claim 21, and dependent claim 10 has been rewritten as added claim 22. Independent claims 1, 16, and 17 of the application have been amended to more clearly define and describe the structure of the lip element of the invention. All claims, including added claims 21 and 22, are considered in good form for allowance. The applicants respectfully request reconsideration of the claims in view of these amendments and the following remarks.

The primary reference upon which the Office Action relies is the Neward '944 patent, which relates to a vacuum extractor having a full lining. As the '944 patent is likewise assigned to the assignee of the present application, a vacuum extractor constructed in accordance with teachings of the Neward '944 patent, as well as a sample of a vacuum extractor constructed in accordance with teachings of the present invention, are enclosed for the Examiner's consideration. As may be seen, both in the prior art sample and the '944 patent, the lined

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Neward cup contains a separately molded, bell-shaped lining, which is assembled into the bell-shaped vacuum cup. The liner 30 lies adjacent the entire length of the cup side wall and closed end portion. As may be understood from viewing the cup, as well as reading the background portion of the application specification, e.g., page 2, lines 18-30, the liner occludes vision through the cup, which may make it difficult to visually determine if the cup is properly positioned on the child's head or to visually monitor the fetal tissue during delivery. As indicated in column 3, lines 24-38 of the '944 patent, the liner 30 includes openings 46 through which pegs 42 extending from the base 40 of the cup protrude. The disk 44 is then placed over the pegs 42 and sonically welded to the disk 44, not only to secure the disk 44 to the pegs 42, but to couple the liner 30 to the cup 10. This coupling of the liner to the cup is specifically claimed in each of the claims of the Neward '944 patent.

In sharp contrast, the lip of the applicants' claimed structure is secured to the side wall edge of the cup, rather than being coupled to the base section of the cup. In this regard, the lip does not extend along the interior up to the base section of the cup. Rather, the lip includes an inner proximal edge which terminates substantially at the side wall edge or subjacent the side wall (as shown in the application drawings and the submitted sample), rather than extending to the base section.

More particularly, claims 1 and 17 have been amended to specifically claim the termination of the lip along the inside

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surface of the side wall, or at the side wall edge. Claim 1 is directed to an obstetrical vacuum comprising "a lip formed of a polymeric second material, ... being secured along said side wall edge adjacent the cup opening, the lip having an inner proximal edge terminating substantially at the side wall edge or subjacent the side wall." Claim 16, which has been similarly amended, is likewise directed to an obstetrical vacuum extractor comprising "a post-molded lip on the outwardly flaring edge of the vacuum cup, the lip having an inner proximal edge terminating substantially subjacent the outwardly flaring edge." Finally, claim 17 is directed to a method of making such an extractor, which comprises the step of "molding a lip of a polymeric second material along the cup opening, the lip having an inner proximal edge terminating substantially at the distal edge or subjacent the side wall."

As may be seen in the physical sample of the prior art, the inner soft liner occludes vision through the interior of the cup. In contrast, as may be seen in the sample constructed according to teachings of the invention, because the inner proximal edge of the lip terminates along the side wall or at the side wall edge, there is no second structure to interfere with or distort vision through the cup during delivery.

Accordingly, inasmuch as the lip terminates before it even reaches the base section of the cup, it cannot be attached as taught in the '944 patent, and cannot be anticipated by the '944 patent. Moreover, it is not rendered obvious by the '944 patent or the '944 patent in conjunction with the Neward '086 patent. Rather, the Neward '944 patent teaches providing a

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complete, soft flexible coating along the inside of the vacuum cup and the cup edges to provide maximum comfort to the patient during application and use. The '944 patent provides absolutely no indication that this comfort might be obtained by less than a complete liner in the cup. Rather, the clear indication is that a full liner must be provided and must be coupled to the cup at the cup's base portion. While it indicates that the liner could further be welded or cemented to the rim 24 of the cup 10 (col. 3, ll. 8-10), the '944 patent requires that the liner completely line the cup and be coupled at the base sections of both cup and the liner. Moreover, the '944 patent indicates that the inventor of the '944 patent, Mr. Neward, tried providing different structures such as providing a bead along the edge of the cup, but found them inadequate for the desired goal (col. 2, ll. 56-66). Accordingly, the '944 patent actually teaches away from the invention in that it teaches that a modification along the edge 24 of the cup is insufficient to satisfy the stated goals of flexibility and the provision of a good seal.

Similarly, there is nothing in the '086 patent which even acknowledges the desirability of utilizing a cup having a flexible edge portion. Rather, the '086 patent indicates only that the cup portion 30 has a bowl-shape having a ridge 40 with a smooth or rounded contour around the outer rim of the open end thereof and that the open end of the cup 30 has a smooth, rounded contour to provide a gentle and effective contact with the scalp of the child (col. 2, ll. 30-39). Thus, the '086 patent teaches that a smooth or rounded contour around the

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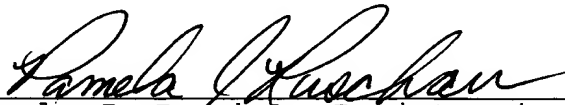
outer rim is desirable, but provides absolutely no indication or acknowledgement of the desirability of utilizing a softer molded material along this rim, much less molding a lip of the particular structure claimed in the independent claims of the application. Rather, it appears that the inclusion of a bead along the cup edge is intended to provide maximum comfort to the mother and child, and, as such, teaches away from the use of a separately molded softer material along the cup edge. Accordingly, neither the '944 patent nor the '086 patent, alone or in combination, teach or render obvious the applicants' claimed invention.

CONCLUSION

The application is considered in good and proper form for allowance, and the Examiner is respectfully requested to pass this application to issue.

If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,



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